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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,862	07/17/2003	Alfonso Ganan-Calvo	AERX-063CON4	6410

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EXAMINER	
LEWIS, AARON J	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 06/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/623,862	GANAN-CALVO, ALFONSO	
	Examiner	Art Unit	
	AARON J. LEWIS	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) . Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knight et al. ('911).

As to claim 21, Knight et al. disclose a method of delivering an aerosol to a patient, comprising: forcing a pharmaceutically active liquid (38) through a channel (32,34,36) of a feeding source in a manner which causes the liquid to be expelled from an exit opening (42,44) of the feeding source; forcing a gas (col.4, line 44) through a pressure chamber (28,30) in a manner which causes the gas to exit the pressure chamber from an exit orifice (42,44) in front (i.e. inasmuch as the gas suctions liquid from reservoir 38 by first passing through exit orifice 42,44 in front of a flow of liquid which is aspirated from reservoir 38; col.4, line 68-col.5, line 3) of a flow path of the liquid expelled from the exit opening of the feeding source. As to the steps of forming a stable liquid-gas between the liquid and the gas whereby the liquid forms a stable liquid jet focused on the first exit orifice of the pressure chamber; allowing the liquid jet exiting the exit orifice to form evenly shaped drops, Knight et al. (col.3, lines 48-55 and col.5, lines 42-53) disclose the generation of a steady stream of small particles 95% of which are less than 5 microns in diameter; therefore, it stands to reason that a stable liquid gas is formed

between the liquid and gas and that the liquid jet exiting the exit orifice is formed of evenly shaped drops (i.e. 95% of the drops are less than 5 microns diameter).

As to claims 22-24, the particular medicament that is selected to be nebulized using the device and method disclosed by Knight et al. includes a variety of medicaments having varying viscosities. The viscosity of a chosen medicament can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular viscosity. Further, Knight et al. teach a pressure regulator (14) for controlling pressure and flow of gas to pressure chamber (28). It would have been obvious to employ the pressure regulator (14) to achieve any desired pressure and flow including 0.01 nl/sec to about 100 microliter/sec. and forced through the opening of the pressure chamber at a rate in the range of from about 100-500 m/sec. in dependence upon the physical condition, age and size of a given patient.

As to claims 25, the diameters of the exit ports (42,44) and exit port of conduit (20) as illustrated in figs.1 and 2 of Knight et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular diameter including 0.002 to about 2mm. One of ordinary skill would realize the necessity of modifying the diameters of the ports in order to control the relative amounts of gas and medicament being aserosolized, which amounts vary in dependence upon the patient's age, size and physical condition.

As to claims 26 and 27, the diameters of the channels (32,34,36) as illustrated within the nebulizer head of fig.2 of Knight et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular

diameter including 0.01 to about 0.4mm. One of ordinary skill would realize the necessity of modifying the diameters of the channels in order to control the relative amounts of gas and medicament being aserosolized, which amounts vary in dependence upon the patient's age, size and physical condition. Further, the spacing between the exit openings (42,44) of Knight et al. of the first means and second fluid exit port (opening of conduit 20 into nebulizer head 30) is illustrated in fig.2 as being closely spaced. The particular spacing can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular spacing including 0.002mm to 2.0mm. One of ordinary skill would realize the necessity of controlling this spacing in order to control the strength of aspiration of liquid medicament from reservoir 38 in an effort to control the concentration of medicament being delivered to a patient.

As to claim 28, Knight et al. disclose a method of delivering aerosolized particles of a pharmaceutically active drug to a patient, comprising: feeding liquid formulation (38) comprised of a pharmaceutically active drug through a liquid feeding source to an outlet (42,44); feeding gas (col.4, line 44) through an orifice positioned in front of the outlet in a direction aligned with a direction of flow of the outlet (figs.1 and 2). As to the steps of maintaining the feeding of liquid and feeding of gas are each at a rate relative to each other so as to maintain a stable capillary microjet of liquid which exits the orifice; and allowing the liquid microjet to form aerosolized particles having a size in the range of about 0.1 micron to about 10 microns, Knight et al. (col.3, lines 48-55 and col.5, lines 42-53) disclose the generation of a steady stream of small particles 95% of which are

less than 5 microns in diameter; therefore, it stands to reason that a stable capillary microjet is formed between the liquid and gas and that the liquid jet exiting the exit orifice is formed of evenly shaped drops (i.e. 95% of the drops are less than 5 microns diameter which is within the claimed range of 0.1 micron to about 10 microns).

As to claims 29 and 30, the particular medicament that is selected to be nebulized using the device and method disclosed by Knight et al. includes a variety of medicaments having varying viscosities. The viscosity of a chosen medicament can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular viscosity. Further, Knight et al. teach a pressure regulator (14) for controlling pressure and flow of gas to pressure chamber (28). It would have been obvious to employ the pressure regulator (14) to achieve any desired pressure through the opening of the pressure chamber that is necessary to achieve the generation of a particular particle size and consistency in an aerosol stream. Further, such parameters also depend upon the physical condition, age and size of a given patient.

As to claims 31-33, Knight et al. as discussed above, disclose the generation of a steady stream of small particles 95% of which are less than 5 microns in diameter. Since the vast majority, 95% of these particles, are less than 5 microns in size, the overall droplet size would have been considered as uniform by one of ordinary skill and any size deviation is within the claimed size standard deviation of 3-30%; further, disclosed particle size less than 5 microns falls within the claimed size range of 1-5 microns.

As to claim 34, fig.2 of Knight et al. illustrates gas causing liquid medicament to exit ports (42,44) as aerosol droplets. Inasmuch as the gas is acting on the liquid at a 90 degree angle, it stands to reason that at least some of the gas includes tangential sweeping forces that act to aspirate liquid medicament and create aerosol droplets.

As to claim 35, Knight et al. disclose inhaling particles via mask (50).

As to claim 36, while Knight et al. disclose liquid medicaments other than water, it stands to reason that any medicament which is known to be administered to a patient's body via the respiratory tract may be administered by the device of Knight et al. including water. One of ordinary skill would have recognized the necessity of providing a humidified stream of breathable air to prevent drying out of respiratory passages during extended periods of treatment.

Claim 37 is substantially equivalent in scope to claim 21 and is included in Knight et al. for the reason set forth above with respect to claim 21. As to the claimed range of viscosities (0.0004 to 1kg/m/sec) of the formulation, the particular medicament that is selected to be nebulized using the device and method disclosed by Knight et al. includes a variety of medicaments having varying viscosities. The viscosity of a chosen medicament can be arrived at through mere routine obvious experimentation and observation with no criticality seen (i.e. applicant has not disclosed criticality for any particular range of viscosities) in any particular viscosity. Further, inasmuch as the medicaments administered to a patient's respiratory tract may be intended for administration to any portion of the respiratory tract from pharynx to alveoli, it stands to

reason that the viscosity of the particular medicament employed would have to be selected so that it would deposit at a desired point.

Claims 38 and 39 are substantially equivalent in scope to claims 22-24 and are included in Knight et al. for the reasons set forth above with respect to claims 22-24.

Claims 40-42 are substantially equivalent in scope to claims 25-27 and are included in Knight et al. for the reasons set forth above with respect to claims 25-27, respectively.

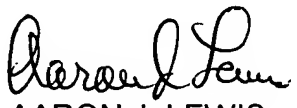
Conclusion

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of the art is cited to show relevant methods for aerosolizing an aerosol to a patient.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (571) 272-4795. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



AARON J. LEWIS
Primary Examiner
Art Unit 3743

Aaron J. Lewis
June 20, 2005